REMARKS

Applicants respectfully request entry of the Amendment and reconsideration of the claims. Claims14 and 15 have been amended. Support for these amendments can be found throughout the specification, including at page 9, lines 22-29 and at page 10, lines 1-11. No new matter has been added through the amendments. Applicants acknowledge withdrawal of the rejections under 35 U.S.C. §§ 102(b), 103(a), and 112, second paragraph.

Upon entry of the Amendment, claims 6-18, 21-25, and 29-31 will be pending. Applicants respectfully request reconsideration and withdrawal of the pending rejections under 35 U.S.C. § 112, first paragraph.

Status of the Claims

Claims 6 to 18, 21 to 25 and 29 to 31 are presently pending. Claims 7, 18, 22, 29 and 30 have been withdrawn from further consideration as being drawn to non-elected species. Claims 6-17, 21, 23 and 24 have been examined in part to the extent that the claims read on non-insulin dependent diabetes and claims 25 and 29-31 have been examined on merit. Claims 14 and 15 have been amended to more clearly define the claimed invention.

Claims Withdrawn

The Examiner stated that claims 7, 8, and 22 have been withdrawn from further consideration as being drawn to non-elected species. As the Examiner has withdrawn claim 7 as being directed to non-elected subject matter, claims 29 and 30 have also been withdrawn as they depend upon claim 7.

Rejection under 35 U.S.C. § 112, first paragraph

The Examiner rejects claims 6, 8-17, 21, 23-25 and 29-31 under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. Applicant respectfully traverses.

Claim 6 has been amended to delete the recitation of "combination of". Claims 14-15 have been amended to delete the recitation of "mixtures thereof" and to change "comprises" back to the original recitation of "is at least one of". Thus, the Examiner's rejection due to the recitation of "mixtures thereof" is now moot.

Further the claimed pharmaceutical composition comprises a) a therapeutically effective amount for reducing insulin resistance of a hepatic glutathione increasing compound and b) a therapeutically effective amount for reducing insulin resistance of a hepatic nitric oxide-increasing compound. Neither the method nor the composition claim an agent that reduces insulin resistance caused by administering a hepatic NO increasing compound. Applicants respectfully assert that the Examiner has misinterpreted the claim to include a limitation that is not present.

In view of the foregoing, Applicnats respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph.

Further Argument:

Lack of *Ipis Verbis* Support

The Examiner stated that as amended, the claims call for the administration of agents that will reduce insulin as a result of hepatic increasing compound and hepatic NO increasing compound. The Examiner stated that the specification lacks *ipis verbis* support that for the claims as amended.

As the Examiner acknowledges that newly added claims or amendment can by supported by implicit disclosure or inherent disclosure, it is respectfully submitted that the Examiner's rejection is moot in view of the reasons set out below. As discussed in further detail below, it is respectfully submitted that the claims are supported by the specification as originally filed as required by the first paragraph of 35 U.S.C. § 112.

The Examiner further stated that the term "mixtures thereof" in claims 14 and 15 lacks *ipis verbis* support in the specification as originally filed. Recitation of "mixtures thereof" has

been deleted in claims 14 and 15.

Lack of Implicit Support

The Examiner acknowledged that exact terms need not be used in *haec verba* to satisfy the written requirement of the first paragraph of 35 USC 112. The Examiner stated that newly added claims or amendment can be supported by implicit or inherent disclosure. The Examiner stated that the claims as amended lacks implicit support in the specification to corroborate the claims as recited. The Examiner stated that the amended claim recites limitations that are contrary to the originally claimed invention and lacks implicit support in the specification at the location specified by the applicant and elsewhere in the application. The Examiner stated that the disclosure referred to by the Applicant in the previous response exemplify that any glutathione increasing compound and any NO increasing compound can be employed. The Examiner further stated that this section of the specification dwells on the dosage requirement for these agents that is not toxic but reduces insulin resistance in a patient. The Examiner stated as amended, the claims call for the administration of agents that will reduce insulin resistance as a result of hepatic glutathione increasing compound and hepatic NO increasing compound. The Examiner stated that the amended claims imply administration of therapeutically effective amount of "any agent" for reducing insulin resistance as a result of administering a hepatic glutathione increasing compound and "any agent" for reducing insulin resistance as a result of administering a hepatic NO increasing compound. The Examiner stated that the specification is limited to treatment of insulin resistance by administering glutathione increasing compound and NO increasing compounds but is silent with respect to agents that reduce insulin resistance caused by glutathione and NO increasing compounds. The Examiner stated that the support provided in the specification is for administration of glutathione increasing and NO increasing compounds and not for agents that affect insulin resistance as a result of administering glutathione increasing and NO increasing compounds.

It is respectfully submitted that the claims are fully supported by the description. Claim 6

as previously presented recites:

A pharmaceutical composition comprising a combination of a therapeutically effective amount for reducing insulin resistance of a hepatic glutathione increasing compound and a therapeutically effective amount for reducing insulin resistance of a hepatic nitric oxide-increasing compound.

Contrary to the Examiner's assertion, the claim is not directed to the use of "agents that will reduce insulin resistance as a result of hepatic glutathione increasing compound and hepatic NO increasing compound". It appears that the Examiner has misread the phrase "of" to mean "caused by". The term "of" is used here in its common usage, a function word to indicate that the following term (e.g. "hepatic glutathione increasing compound") is qualified by the preceding term (e.g. "a therapeutically effective amount for reducing insulin resistance"). The claimed pharmaceutical composition comprises a combination of a hepatic glutathione increasing compound and a hepatic nitric oxide-increasing compound. This would be clear to the person skilled in the art having regard to the claims in isolation and in the context of the specification as a whole. The specification clearly discloses the use of a hepatic glutathione increasing compound together with a hepatic nitric oxide increasing compound for the treatment of insulin resistance (see for example, page 6, lines 18-21 of the description). Claim 6 further defines that each of the hepatic glutathione increasing compound and the hepatic nitric oxide increasing compounds are present in the claimed pharmaceutical composition in an amount which is therapeutically effective for reducing insulin resistance. Thus, it is clear to the skilled reader that the active agents of the claimed pharmaceutical composition are the hepatic increasing compound and the hepatic nitric compound. It is these active agents which have the therapeutic effect of reducing insulin resistance. These active agents do not cause insulin resistance but instead prevent or treat insulin resistance. Claims 9 and 10 are directed to methods of treatment which are restricted to the administration of the pharmaceutical composition of claim 6. Thus, the Examiner is incorrect to assert that the amended claims imply administration of therapeutically effective amount of "any agent" for reducing insulin resistance as a result of

administering a hepatic glutathione increasing compound and "any agent" for reducing insulin resistance as a result of administering a hepatic NO increasing compound. Furthermore, the Examiner's allegations that the specification fails to provide implicit support for agents that affect insulin resistance as a result of administering glutathione increasing and NO increasing compounds are moot as the present invention is not directed to the treatment of insulin resistance caused by the administration of hepatic glutathione increasing and hepatic NO increasing compounds. As stated above, the present invention is directed to the use of hepatic glutathione increasing and hepatic NO increasing compounds as active ingredients for the treatment of insulin resistance. As the Examiner acknowledges that the specification provides support for the treatment of insulin resistance by administering glutathione increasing compound and NO increasing compounds (see page 7, 1st paragraph, lines 14-15 of the office action), reconsideration and withdrawal of the Examiner's objection is respectfully requested.

The Examiner stated that the specification lacks any implicit support that would support the terms "mixtures thereof" (claims 7, 14 and 15). The Examiner stated that the location specified by the applicants in the previous response and elsewhere in the application, does not provide implicit support for the term "mixtures thereof". The Examiner stated that implicit support for the term "mixtures thereof" is lacking because only place where more than one compounds was mentioned was on page 10, line 9, that is drawn to "one or both compounds" in the alternative and that the Examples disclosed in the specification are limited to administering one glutathione increasing compound and one NO increasing compound. The Examiner stated that the term "mixtures thereof" imply the presence of more than one glutathione increasing compounds with one NO increasing compounds and vice versa. The Examiner stated that the disclosure does not imply additional glutathione -increasing compounds were administered with one NO increasing compound and vice versa. The Examiner concluded that the claims as amended do not have implicit disclosure support in the specification and hence constitute new matter.

Claim 7 has been withdrawn. Claims 14 and 15 have been amended to revert back to the

claim language as originally filed. In view of the present amendments and the reasons set out above, it is respectfully submitted that the Examiner's objection has been rendered moot.

Interview Request

Applicants request an interview with the Examiner.

Summary

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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